C-Path Appoints Co-Directors to CURE Drug Repurposing Collaboratory Advisory Committee

TUCSON, Ariz., February 4, 2021 — Critical Path Institute (C-Path) today has announced the appointments of David Fajgenbaum, M.D., M.S., M.B.A., and Marco Schito, Ph.D., as co-directors of the advisory committee for C-Path's CURE Drug Repurposing Collaboratory (CDRC) program.

"On behalf of the FDA's Center for Drug Evaluation and Research (CDER), we applaud the appointments of Drs. Fajgenbaum and Schito to the leadership of C-Path's CURE Drug Repurposing Collaboratory advisory committee," said Jacqueline Corrigan-Curay, M.D., J.D., director of CDER's Office of Medical Policy. "These individuals have expertise and dedication to help advance CURE ID's goal of using real-world data to identify drugs that may have the potential to be repurposed for new diseases and to guide clinical trials that can establish the evidence needed to ultimately bring therapies to the patient's bedside sooner."

CDRC — a public-private partnership — provides a forum for the exchange of real-world clinical practice data to inform future clinical trials of existing drugs for diseases with high unmet medical need. This global effort aims to advance research in drug repurposing through the creation of a network that connects major treatment centers, academic institutions and researchers, private practitioners, government facilities and health care professionals. CDRC captures relevant real-world clinical outcome data through the CURE ID platform. CDRC is funded by U.S. Food and Drug Administration (FDA) in collaboration with the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH).

Dr. David Fajgenbaum is the co-founder and executive director of the Castleman Disease Collaborative Network (CDCN) and one of the youngest individuals to be appointed to the faculty at the University of Pennsylvania where he directs the Center for Cytokine Storm Treatment & Laboratory (CSTL). An NIH-funded physician-scientist, he has dedicated his life to discovering new treatments and cures for deadly disorders like idiopathic multicentric Castleman disease (iMCD), which he was diagnosed with during medical school. He has also been on the forefront of applying business-inspired solutions to drive forward iMCD research and working to turn this innovative model into a blueprint for accelerating rare disease research and drug repurposing.

Dr. Fajgenbaum described his journey in his national best-selling book, “Chasing My Cure: A Doctor’s Race to Turn Hope into Action.” In March 2020, he re-directed the CSTL and CDCN to identify and track all reported treatments for COVID-19. The team’s analysis is publicly available in a database called the Covid-19 Registry of Off-label & New Agents (CORONA) Project and is shared with CURE ID. Since Fajgenbaum joined CDRC, it has built out a Coordinating Committee and COVID-19 working group made up of experts in a range of medical specialties.

“My life’s mission is to make sure that every single FDA-approved treatment is repurposed for every other disease where it could be effective. I’m alive because of a repurposed drug, and I want to do all that I can to ensure more patients can benefit from these therapies,” said Fajgenbaum.

Dr. Marco Schito is executive director of CDRC at C-Path and an adjunct professor at the University of Arizona, James E. Rogers College of Law. His work aims to discover potentially safe and effective repurposed therapies for diseases with high unmet medical need by capturing and sharing global real-world clinical data. Prior to joining C-Path, Dr. Schito was a senior scientific officer at the Division of AIDS, NIH, where he led and managed molecular point-of-care diagnostic contracts for HIV viral load assays in low-resource settings, stood up a fully characterized HIV global viral diversity panel program, and launched a research initiative to standardize the measurement of mucosal immune responses in HIV clinical trials. During his intramural tenure at the National Cancer Institute, Dr. Schito led the in vivo modeling of anti-retroviral zinc finger inhibitors for antiviral microbicide applications.

While at C-Path, Dr. Schito established a data knowledge base to enable the use of next-generation sequencing platforms to quickly and accurately identify efficacious tuberculosis drug regimens based on the interpretation of drug resistance mutations. The World Health Organization is using this platform for its global genomic drug surveillance program.

“At C-Path, we believe that cross-disciplinary collaboration is a key factor in innovation, and David and Marco understand that better than anyone,” said John-Michael Sauer, Ph.D., C-Path Biomarkers Program Officer. “Their substantial knowledge and experience in the fields of rare disease research and immunology, respectively, will be invaluable as CDRC grows and evolves as a driver of innovation for the global scientific community.”

*Critical Path Institute is supported by FDA of the U.S. Department of Health and Human Services (HHS) and is **69%** funded by FDA/HHS, totaling **$19,471,171**, and **31%** funded by non-government source(s), totaling **$8,612,313**. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government.*

CRITICAL PATH INSTITUTE

Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path’s mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader

in forming collaborations, C-Path has established numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path US is headquartered in Tucson, Arizona and C-Path, Ltd. EU is headquartered in Dublin, Ireland, with additional staff in multiple other locations. For more information, visit c-path.org and c-path.eu.

CURE ID
Challenging cases... New approaches

CURE ID is a web-based data collection application that summarizes and shares high-level clinical outcome information through a standardized case report form. It allows the clinical community to report real-world data on the novel use of existing drugs for difficult-to-treat infectious diseases. Clinicians and other users can freely access this repository and can view aggregated datasets as well as the individual case reports. By systematically capturing these data from health care providers, CDRC can inform and facilitate drug repurposing efforts. This effort can potentially benefit patients by using real-world evidence to inform the design of clinical trials and eventually further drug development.

FDA and NCATS have made critical updates to CURE ID to be a more effective tool in the COVID-19 public health emergency. These updates allow clinicians to more easily report their real-world experiences treating COVID-19 patients who are unable to be enrolled in a clinical trial.

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